

It is requested in view of the following discussions that all now reported rejections be reconsidered and not repeated in any further action issued for this application.

Claim Rejections – 35 USC § 103

Rejections under 35 USC § 103(a) are reported in the final action as being directed to: (i) claims 27, 28, 31, 35-37 and 39 for being unpatentable over U.S. Patent No. 5,425,376 (Banys et al.) in view of U.S. Patent No. 6,574,497 (Pacetti); and (ii) claims 29, 32 and 38 for being unpatentable over Banys et al. in view of Pacetti, and in further view of U.S. Patent No. 4,588,399 (Nebergall et al.). These reported rejections are traversed as is discussed below.

Prior prosecution of this application includes a Response to Non-Final Office Action that was filed on November 21, 2005. The now outstanding final action was next mailed. This final action reports that the claim amendments and arguments submitted by the November 21, 2005 filed Response “have been considered but are moot in view of the new ground(s) of rejection.” (Final Action, paragraph 5). These new ground(s) of rejection are the section 103 rejections addressed here.

Claims 27, 31 and 35 of reported rejected claims are independent, all other reported rejected claims are dependent from one or the other of these three independent claims. Attention now will be directed to these three independent claims, because if an independent claim recites allowable subject matter, then all claims dependent from that independent claim also recite allowable subject matter.¹

Explicit subject matter read on by claims 27 and 31 are recited methods for use of endoscopes having a tissue cutting device extendable from a distal portion of a lumen, *i.e.*, a cavity or channel in a catheter. These limitations are identically set out in the preamble of both of these independent claims as follows: “Method for determining length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscope catheter, which comprises....”

¹ “Dependent claims are nonobvious under 103 if the independent claims from which they depend are nonobvious.” (Citations omitted) *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Endoscopes are well known medical devices that those skilled in the art understand to be “an instrument for the examination of the interior of a hollow viscus”² Remaining recited limitations for these two claims include those directed to processes for providing a plurality of radiopaque indicia at measurable intervals along a length of the tissue cutting device and radiologically determining the length of deployment from or exposure from the distal portion of the lumen.

Explicit subject matter read on by the remaining independent claim — *i.e.*, claim 35 — is a “catheter having at least one lumen.” This catheter apparatus as claimed includes limitations for: a “tissue cutting device disposed in said lumen”; the “tissue cutting device having a cutting member disposed for extension out of ... said lumen”; and, “at least one radiopaque indicia disposed on said tissue cutting device ..., wherein the length of said cutting member is extended from said opening is a length said radiopaque indicia is moved in said lumen.”

Against these explicit recited limitations and in contrast, the primary asserted reference, *i.e.*, Banys et al., discloses:

A tool ... for taking a biopsy sample, having a needle attached to a syringe, with an opening in the side of the needle, which can be selectively covered by a cannula slidably mounted over the needle. ... A method is also disclosed for taking a biopsy sample by sliding a cannula over a needle, inserting the cannula and needle into the tissue to be sampled, partially withdrawing the cannula from the needle to expose a lateral opening in the needle, maneuvering a sample of the tissue into the opening, cutting the sample from the tissue, and drawing the sample out through the needle. (Abstract)

Banys et al. disclose that “cutting the sample from the tissue” can be done either with the lateral opening that “can have a sharp edge along at least one edge of the opening” (col. 2, lines 45-48), or “[t]he cannula can also have a sharp edge on its distal end, so that advancing the cannula along the needle can cut off the tissue sample that has been maneuvered into the lateral opening of the needle.” (col. 2, lines 52-56). With respect to maneuvering tissue “into the lateral

² Dorland’s Illustrated Medical Diction, 28th Edition, W.B. Saunders Co., Philadelphia, 1994, p. 555.

opening of the needles,” Banyas et al. disclose that a “physician can maneuver the distal end of a needle 16, which can be radiopaque for ease of viewing, to place a sample of tissue within opening 28 of needle 16.” (col. 16, lines 7-10, also cited in Final Action, paragraph 3).

Based on the independent claim recitations and Banyas et al. disclosures, it is asserted in the final action that Banyas et al. “teaches the cutting device being radiopaque, [but] fails to teach the radiopaque material arranged as a plurality of radiopaque indicia at measurable intervals.” (Final Action, paragraph 3). Banyas et al. indeed do fail to disclose a plurality of radiopaque indicia. Banyas et al., however, also fail to disclose a cutting device as such being radiopaque, because Banyas et al. disclose that the “needle 16” having a “lateral opening 28” is maneuvered using some radiopaque feature “to place a sample of the tissue within opening 28 of needle 16.” The use of a radiopaque feature exclusively is disclosed by Banyas et al. for the purpose of placing a tissue sample in an opening provided on a needle. There is no suggestion of using a radiopaque feature for determining or measuring displacement from a lumen of any cutting device. These facts compound that Banyas et al. fail to disclose or provide inherent teachings that concern or effect relation to independent claim recited subject matter such as: endoscopes; catheters; tissue cutting devices extendable from catheter lumens; or use of radiology for determining any length a tissue cutting device is extended from a distal portion of a lumen. Such failures, it is submitted, not only go beyond and compound over the single failure acknowledged in the final action, they effectively render Banyas et al. a non-relevant reference with respect to the subject matter recited in the claims.

These Banyas et al. failures are not overcome or even addressed by Pacetti or Nebergall et al.

Turning first to Pacetti, this patent discloses use of fluorine-19 as a magnetic resonance imaging (MRI) medical device marker. It is asserted in the final action that Pacetti discloses “a cutting device (needle, see abstract) with a plurality of radiopaque indicia at measurable intervals....” (Final Action, paragraph 3). Upon reference to Pacetti, it was found that disclosure of a needle is made at three places in the patent. Specifically, in the abstract, at col. 4, lines 12-

26, and at col. 6, line 61, to col. 7, line 7. Substantively, each of these disclosures state that fluorine-19 can be used as a marker of a device, *i.e.*, some medical device, and “may encompass the device partially or wholly, meaning the entire device may be partially, or wholly, constructed of a fluorine containing material.” (col. 4, lines 13-17). Examples of such medical devices include seventeen listed devices, such as biopsy needles. In fact, each time a needle is referenced in the patent, that structure is specified as being a “biopsy needle.” Included in the final action assertions concerning this patent are references to Pacetti figures; specifically, Figs 3 and 10 are referenced. Pacetti identifies both of these figures as showing catheters and not cutting devices. Figure 3 is specified as depicting “a partial perspective view of an embodiment of a catheter tube including a plurality of marker bands....” (col. 5, lines 14-16). Figure 10 is specified as depicting “a longitudinal cross-section view of a catheter tube having a passive marker material dispersed within the wall of the catheter.” (col. 5, lines 32-34). Accordingly, it is traversed that Pacetti discloses or suggests providing a plurality of radiopaque indicia for a cutting device, because Pacetti instead discloses that a catheter tube can be provided with a plurality of marker bands.

Next turning to Nebergall et al., this patent discloses cannulae with radiopaque tips. It is asserted in the final action that “it would be obvious to one of ordinary skill in the art to use a cannula having a radiopaque tip, such as the one taught by Nebergall, because in order to determine the location of the cutting device relative to the cannula, it would be necessary to use the cannula as a reference point.” (Final Action, paragraph 4). In context of independent claim recited limitations, having a cannula include a radiopaque tip is not relevant. What is relevant is discussed above, and the Nebergall et al. reference in fact is only cited in the final action with respect to reported rejections of dependent claims 29, 32 and 38. Such rejections are overcome, as discussed above, if the base independent claims are nonobvious.

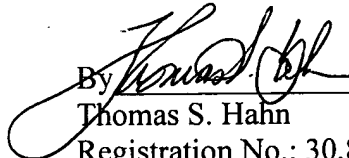
It is submitted that the base independent claims indeed are nonobvious for at least the reasons set forth above.

CONCLUSION

It is believed that all pending claims are in condition for allowance and a notice of the same is requested. Should the Examiner have any questions, requests or suggestions, he is invited to contact the undersigned attorney at the telephone number set out below.

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Respectfully submitted,

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